



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,106	01/27/2004	Danny Lewis	PRJ-006CN	2190

959	7590	09/19/2007
LAHIVE & COCKFIELD, LLP		
ONE POST OFFICE SQUARE		
BOSTON, MA 02109-2127		

EXAMINER	
AZPURU, CARLOS A	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
09/19/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/766,106	Applicant(s) LEWIS ET AL.	
	Examiner Carlos A. Azpuru	Art Unit 1615	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 June 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 12-16, 19, 20, 23 and 24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12-16, 19, 20, 23 and 24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date. _____   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Receipt is acknowledged of the request for reconsideration filed 06/26/2007.

The rejections under 35 USC 112, first paragraph for written description and enablement are hereby withdrawn in view of applicant's amendments.

The following rejection is maintained in this action:

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 12-16, 19, 20, 23, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kinstler et al.

Kinstler et al. N-terminally chemically modified CSF and IFN by N-terminal monopegylation (see col. 10, lines 38-67). These modified peptides are then incorporated into particulate preparations of polymeric compounds such as polylactic acid, polyglycolic acid or liposomes (see col. 11, lines 55-58). The teachings of Remington's Pharmaceutical Sciences, 18<sup>th</sup> Ed at col 11, line 61 includes microencapsulation at page 1663. The size of the particles formed by this process range from several tenths of a  $\mu\text{m}$  to 5,000  $\mu\text{m}$ . Alpha-interferon is specifically recited at col. 11, line 1. Those of ordinary skill would have found it well known to conjugate interferons or CSF with polyethylene glycol, and further to microencapsulate said conjugated bioactives in a biodegradable polymer such as polylactic or polyglycolic acids, and further to expect similar therapeutic results from the use thereof given the teachings of Kinstler et al. The instant invention would have been obvious to one of ordinary skill at the time of invention given the teachings of Kinstler et al.

### ***Response to Arguments***

Applicant's arguments filed 06/26/2007 have been fully considered but they are not persuasive.

With regard to the rejection under 35 USC 103(a) over Kinstler, applicant argues that the reference, although disclosing derivatization of interferon with polyethylene glycol, does not form a monophasic. However, as in the instant claim, Kinstler derivatizes the IFN using a hydrophilic polymer and discusses its homogenous property in col. 9, line 36. This inherently entails a "monophasic".

Further applicant argues that the reference does not disclose formation of microparticles or nanoparticles. However, the citation at col. 11, lines 55-58 not only includes a specific teaching of the formation of particles, but incorporates by references the section of Remington's which teaches microencapsulation.

While applicant focuses on the fact that Remington's does not disclose a biodegradable polymer, it is used only for its generic teaching of microparticles formation. The specific polymers used by the reference encompass those of the instant claims. Remington's is cited by the reference for its background teaching in how to form such particles in the broadest sense.

Applicant then focuses on Kinstler's lack of disclosure of the terms "dissolve" and monophasic. However, as pointed out, the reference does include a disclosure of a homogenous preparation of polymer and protein conjugate (col. 9, lines 1-47).

Applicant further argues the reference fails to disclose a biodegradable polymer having hydrophilic and hydrophobic regions (a block copolymer). However, the reference does include both the hydrophilic area (polyethylene glycol) and hydrophobic area (polylactic and polyglycolic acids) separately. Absent a criticality in having both polymers as part of a large block copolymer, those of ordinary skill would have expected similar therapeutic results from using said polymers separately as taught by the reference to form the same conjugate.

Applicant argues that the particle size is not disclosed by the Remington's citation. Specifically, the claimed size between 20 and 100 um is not disclosed. However, applicant acknowledges the broad recitation found in that reference which encompasses tenths of a um to 5000 um which clearly encompasses the claimed particle size as well as art accepted definitions of both nanoparticles and microparticles.

As such, it is believed the instant invention would have been obvious to one of ordinary skill in the art at the time of invention given the teachings of Kinstler et al.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1615

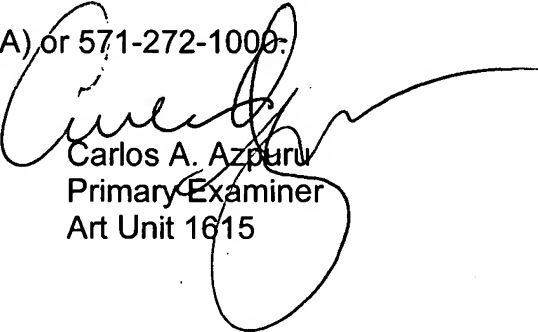
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is (571) 272-0588. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1615

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Carlos A. Azpuru  
Primary Examiner  
Art Unit 1615

caz